STATE OF SOUTH CAROLINA **COUNTY OF RICHLAND**	)	**BEFORE THE CHIEF PROCUREMENT OFFICER**
	)	DECISION
In the Matter of Protest of:	)	
	)	CASE No. 2011 - 111
Rebel Distributors Corporation	)	
Dept. of Health & Environmental Control IFB No. 5400002478 Re-packaging/Re-labeling Medications	)	POSTING DATE: April 11, 2011 MAILING DATE: April 11, 2011

This matter is before the Chief Procurement Officer (CPO) pursuant to a letter of protest from Rebel Distributors Corporation (Rebel). With this invitation for bids (IFB), the Department of Health and Environmental Control (DHEC) attempts to procure services of a Centers for Disease Control (CDC) and Food & Drug Administration (FDA) approved and South Carolina Board of Pharmacy registered pharmaceutical re-packager/re-labeler to repackage and re-label flu vaccines. (Ex. 1) In the letter, Rebel protested DHEC's notice of intent to award to Safecor Health, LLC (Safecor) alleging that Rebel's bid was inappropriately rejected as nonresponsive and non-responsible and Safecor was not a responsible bidder.

In order to resolve the matter, the CPO conducted a hearing March 23, 2011. Appearing before the CPO were Rebel, represented by Ari Greenwald; Safecor, represented by Ryan O'Dell; and DHEC, represented by Julie McIntyre, Esq.

NATURE OF PROTEST

The letter of protest is attached and incorporated herein by reference.

FINDINGS OF FACT

The following dates are relevant to the protest:

1. On January 24, 2011, DHEC issued the IFB. (Ex. 1)

2. On January 25, 2011, DHEC issued Amendment No. 1. (Included with the IFB as Ex. 1)

3. On February 10, 2011, DHEC opened the bids received.

4. On February 17, 2011, after evaluating the bid of Rebel, Michelle Robinson, DHEC Procurement Manager, prepared a written determination rejecting Rebel's bid as non-responsive and non-responsible. (Ex. 4)

5. On February 23, 2011, DHEC posted its intent to award to Safecor. (Ex. 5)

6. On March 7, 2011, Rebel filed its protest with the CPO.

MOTIONS TO DISMISS

At the hearing, DHEC moved to dismiss portions of a memorandum submitted by Rebel prior to the hearing. First, DHEC alleged that Rebel was attempting to raise an additional issue that it should not have been found to be responsive because any non-compliance was a minor informality. Therefore, DHEC moved to dismiss any "ground" regarding a minor informality as untimely. The CPO denied the motion in this regard because Rebel is not attempting to add an additional issue. Rather Rebel is asserting a legal argument, which is permissible and timely.

Second, DHEC also moved to dismiss some of Rebel's grounds as untimely because they allegedly challenged the specifications and therefore should have been protested pursuant to the time limits of Section 11-35-4210(1)(a). To the extent that Rebel is challenging the specifications rather than the responsibility and responsiveness determinations, this motion is granted.

CONCLUSIONS OF LAW

A. Responsibility Issues

In its protest letter, Rebel challenged DHEC's determination that it was a non-responsible bidder on the ground that Rebel's registration with the FDA was not current. Rebel also alleged that Safecor, the intended awardee, did not have a current FDA registration either; thus, the CPO finds Rebel also challenged DHEC's determination that Safecor was a responsible bidder.

Only a responsible bidder may be awarded a contract. S.C. Code Ann. 11-35-1520(10). The Code defines a responsible bidder as one "who has the capability in all respects to perform fully the contract requirements and the integrity and reliability which will assure good faith performance which may be substantiated by past performance." Section 11-35-1410(6). Pursuant to Regulation 19-445.2125(A) promulgated by the South Carolina Budget and Control Board, factors to be considered include whether a prospective contractor has:

> (1) available the appropriate financial, material, equipment, facility, and personnel resources and expertise, or the ability to obtain them, necessary to indicate its capability to meet all contractual requirements;
> (2) a satisfactory record of performance;
> (3) a satisfactory record of integrity;
> (4) qualified legally to contract with the State; and
> (5) supplied all necessary information in connection with the inquiry concerning responsibility.

Moreover, Regulation 19-445.2125(F) also permits the State to require bidders to meet special standards of responsibility where unusual or specialized requirements are needed for contract performance.

According to the South Carolina Procurement Review Panel (Panel), the procurement officer is obligated to determine responsibility before award and may consider any source of information. Protest of CollegeSource, Inc., Case No. 2008-4; See also, S.C. Code Ann 11-35-1810(1); Reg.19-

445.2125(B). A procurement officer's responsibility determination is a matter of discretion and cannot be overturned unless the protestant shows it was "clearly erroneous, arbitrary, capricious, or contrary to law." S.C. Code Ann. 11-35-2410(A). In Protest of Value Options, Case No. 2001-7, the Panel noted that procurement officers are given broad discretion in making their responsibility determinations because these are a matter of business judgment. The Panel explained that "[t]o prove arbitrary and capricious conduct such as will permit the court to overturn a procurement decision, the aggrieved bidder must demonstrate a lack of reasonable or rational basis for the agency decision or subjective bad faith on the part of the procuring officer or clear and prejudicial violation of relevant statutes and regulations which would be tantamount to a lack of reasonable or rational basis." Id., citing Robert E. Derecktor of Rhone Island, Inc. v. Goldschmidt, 516 F.Supp. 1085 (U.S.D.C. Rhode Island 1981).

1. Allegation that DHEC's non-responsibility determination as to Rebel based on its FDA registration was clearly erroneous, arbitrary, capricious and contrary to law

In its protest letter, Rebel protested DHEC's determination that it was non-responsible due to its non-current FDA registration. Rebel stated "Rebel indeed provided the only available hardcopy evidence; our registration from 2006" and claimed that was sufficient. Although it was listed on the FDA website, Rebel admitted that it's FDA website registration was not current at the time that DHEC deemed Rebel non-responsible. However, Rebel argued that the State should not have relied on the FDA website alone to determine whether a bidder had a current registration status.

The IFB required bidders to possess a current FDA and South Carolina Board of Pharmacy registrations and for the FDA registration status to be listed on the FDA website. The IFB read, "The bidder must: Be a FDA and CDC approved and South Carolina Board of Pharmacy registered re-labeler. Company's registration status must be listed on the FDA website at http://www.fda.gov/Drugs/InformationonDrugs.ucm135778.htm." (Ex. 1, p. 14, Specifications, 3.1)

Further, the IFB required that offerors "Provide evidence of current FDA and South Carolina Board of Pharmacy registration." (Ex. 1, p. 16, Information for Offerors to Submit, Item 4.5)

Rebel responded in its bid, "Per specification 3.1 Rebel Distributors Corp. is registered and approved by the FDA & CDC as a re-labeler. Per specification 3.1/3.2 Rebel Distributors Corp. is registered and approved with the South Carolina Board of Pharmacy as a re-labeler." (Ex. 2, p. 5, Scope of Work/Specifications) Rebel also enclosed a copy of a Department of Health and Human Services, Food and Drug Administration, Registration of Drug Establishment/Labeler Code Assignment dated March 31, 2006 showing Rebel Distributing Corp., 3607 Old Coneja Road, Thousand Oaks, CA held registration number 2024591. (Ex. 2, unnumbered pages) In addition, Rebel enclosed a Non-Resident Wholesaler Distributor/Manufacturer Permit issued by the South Carolina Department of Labor, Licensing and Regulation's Board of Pharmacy for 2010/2011. (Ex. 2, unnumbered pages)[1]

In her written determination of non-responsibility, Michelle Robinson of DHEC found as follows:

> Under Paragraph 4.5 of the Solicitation; all offerors were required to provide evidence of current FDA and South Carolina Board of Pharmacy registrations. Rebel Distributors Corporation provided a copy of SC Board of Pharmacy permit but did not provide a copy of a current FDA registration. The offeror's proposal contained only a 2006 FDA registration.
>
> Under Paragraph 3.1, all bidders were required to have their registration status listed on the FDA website (http://www.fda.gov/Drgus/InformationonDrugs/ucm135778) and the link to this website was provided on page 14 in the solicitation. Rebel Distributor's 2009 registration was listed on the FDA's website as their most current registration as verified by the procurement officer prior to releasing the Intent to Award. Per 21 U.S.C. section 510 (b) (1) of the Federal Food, Drug and Cosmetic Act and the implementing regulation, 21 CFR 207.21 (a) owners and operators must renew their registration information annually. Any potentially awarded contractor must be

[1] Rebel's South Carolina Board of Pharmacy permit is not at issue.

> current with their FDA registration in order to be considered a responsible bidder and capable of providing the required services." (Ex. 4)

The CPO finds that the IFB clearly required that each bidder provide evidence of current registrations and that the registrations be verifiable. With the requirement that each bidder's registration status be listed as current on the FDA website, DHEC specified the registrations required of bidders, and advised potential bidders of how DHEC would determine compliance. This requirement qualifies as a special standard of responsibility and meets all requirements of Regulation 19-445.2125(F), which reads:

> When it is necessary for a particular acquisition or class of acquisitions, the procurement officer may develop, with the assistance of appropriate specialists, special standards of responsibility. Special standards may be particularly desirable when experience has demonstrated that unusual expertise or specialized facilities are needed for adequate contract performance. The special standards shall be set forth in the solicitation (and so identified) and shall apply to all offerors. A valid special standard of responsibility must be specific, objective and mandatory.

Rebel contended that DHEC should not have relied on the website to determine whether a bidder has a current registration status. Rebel could have, but did not, protest that requirement of the solicitation. Doing so at this juncture is untimely. More importantly, Rebel did not comply with this very specific requirement in that its registration on the FDA website was not current. According to Ms. Robinson, the FDA website specified in the IFB listed Rebel's most current registration as 2009, meaning the last possible effective date of Rebel's registration with the FDA was December 31, 2010. She offered screen prints from the FDA website as evidence of Rebel's status. (See Exhibit 11.) In determining Rebel's registration status, and thus it's responsibility, Ms. Robinson used the precise tool identified in the IFB - the FDA website. Moreover, 21 U.S.C. 510(1)(b)(1) requires annual registration and the only other documentation that Rebel supplied was a hard copy of its FDA registration from 2006.

Therefore, the CPO finds that Ms. Robinson's determination that Rebel was not responsible, based upon its registration not being current on the FDA's registration website, was not "clearly erroneous, arbitrary, capricious, or contrary to law." S.C. Code Ann. 11-35-2410(A).

2. Allegation that DHEC's responsibility determination as to Safecor was clearly erroneous, arbitrary, capricious and contrary to law

In its protest letter, Rebel alleged further that Safecor "was and still is not listed as current"(ly) registered on the FDA website. At the hearing, Rebel argued that Safecor's registration on the FDA website was also not current because it did not reflect the year of 2011.

However, both DHEC and Safecor contended that Safecor's registration was current when DHEC deemed Safecor responsible. They argued that the FDA requires registration annually and therefore companies must register by the end of the year. According to DHEC and Safecor, a 2010 registration is effective through December 31, 2011 because a 2011 registration is not due until December 31, 2011.[2] With its bid, Safecor enclosed a screen print from the FDA website that indicated Safecor's Drug Firm Annual Registration was updated for the registration year of 2010. (Ex. 10, unnumbered page) In its responsibility determination, DHEC also checked the FDA website to confirm Safecor's current registration status. (Ex. 3)

Based on the evidence presented, Rebel failed to meet its burden of proving that Safecor was not currently registered on the FDA's website. Accordingly, the CPO finds no basis to overturn Ms. Robinson's determination that Safecor was responsible to the requirement that its registration be current with the FDA.

[2] Although not required until December 31, 2011, after the award, Safecor submitted its 2011 registration March 10, 2011.

B. Responsiveness Issues

In its protest letter, Rebel alleged that its bid was responsive and DHEC improperly rejected its bid as non-responsive on numerous grounds.

In order to be awarded a contract, a bidder must be responsive. S.C. Code Ann. 11-35-1520(10). The Code defines a responsive bidder as one "who has submitted a bid...which conforms in all material aspects to the invitation for bids..." Section 11-35-1410(7). According to the Panel, a bid does not need to conform to all of the IFB's requirements in order to be responsive; rather it must merely conform to the essential requirements. See Protest of National Computer Systems, Inc., Case No. 1989-13. In Protest of National Computer Systems, Inc., the Panel explained the deference given to vendors bidding on state contracts as follows:

> The Code is purposely designed to achieve a balance between the need for procuring products and services at the lowest possible price and the need for competition and fair and equitable treatment of all vendors. Unfettered discretion in a procuring agency would bode a return to the pre-Code days when purchasing was for the most part subjective. Too little discretion and too much rigidity in interpreting requirements would result in the intolerable situation of the State's paying more...because of minor technical errors. It is the intent of the Panel...to leave intact this delicate balance.

See also, Protest of Gregory Electric Company, Inc., Case No. 1989-17 (agreeing with result in National Computer Systems that the State must strike a balance when deciding if a bid is responsive.)

1. Allegation that Rebel's bid was responsive to 3.5 b.1) of the IFB, which read "Documentation must be provided that the products were maintained at a temperature control between 20-25 C (68-77 F) at all times."

In her written determination of Rebel's nonresponsiveness, Ms. Robinson found that Rebel was nonresponsive to 3.5.b.1) of the IFB because "Rebel Distributor's did not address the requirement to

provide documentation that the climate control was maintained at all times at the end of the term." (Ex. 4)

However, Rebel argued that this language of the IFB is not requesting any specific documentation but rather it is instruction for what the contractor must do once the product and shipment is complete. The CPO agrees. This specification instructed bidders that "**Documentation must be provided** that the products were maintained at a temperature control between 20-25 degrees C (68-77 degrees F) at all times regards a requirement of contract performance." (Emphasis per the original) DHEC included this requirement under the IFB section entitled "Specifications", not under the IFB section entitled "Information for Offerors to Submit." The IFB does not require such documentation to be submitted with the bids; therefore, it is not a requirement for a bid to be responsive. Moreover, 3.5.1.b.1). is a subsection of 3.5.1.b. that begins with, "If work is performed at vendor's location." Thus it is a post-award contract performance requirement that documentation be submitted by the contractor to DHEC when work is performed at a vendor's location and the medications are returned to DHEC.

Therefore, the CPO finds Rebel's bid responsive to specification 3.5.b.1).

2. Allegation that Rebel's bid was responsive to 4.7 of the IFB, which read "Describe how they will provide documentation that the products were maintained at a temperature control between 20-25 C (68-77 F) at all times including during transit."

Specification 4.7 corresponded with specification 3.5.b.1). referenced above and required bidders describe how they would comply with the temperature control requirement for handling the pharmaceuticals entrusted to their care. Listed under the section of the IFB entitled "Information for Offerors to Submit", this specification required bidders in their bids to "Describe how they will provide

documentation that the products were maintained at (the prescribed) temperature control." Unlike 3.5.b.1). above, this requirement clearly requires bidders to submit documentation with their bids.

In her written determination, Ms. Robinson found Rebel nonresponsive because "Rebel did not provide an adequate description of their process for maintaining the temperature control at all times including during transit." (Ex. 4) Rebel challenges her determination arguing that its bid did describe how it would provide documentation that products were maintained at the prescribed temperature. The CPO agrees. In its bid, Rebel stated as follows:

> Per solicitation sec. IV subsection 4.7, our facility monitors and maintains Temp/Humidity monitors throughout our production and warehousing facilities. Records are maintained for a minimum of three years. In transit temperature controls will feature temperature excursion alerts and temperature control. Documentation is maintained in the shipping manifest. (Ex. 2, p. 5, Temperature Control Documentation Description)

The CPO finds that Rebel's bid was responsive to specification 4.7 because it described Rebel's process for providing documentation that products returned to DHEC were maintained at the prescribed temperature.

3. Allegation that Rebel's bid was responsive to 3.7 of the IFB, which read "Provide a proposed timeline for the completion of this project."

In her determination that Rebel's bid was nonresponsive for failure to provide a proposed timeline for completing the project, Ms. Robinson wrote, "Rebel Distributors did not respond adequately to this requirement; the offeror only acknowledged the start and completion dates as listed below...

> Start date: Start date to begin within 30 days of solicitation award.
>
> Completion date: Re-label/Re-package to be completed by June 1, 2011 or sooner." (Ex. 4)

Rebel argues that it provided an adequate proposed timeline. The CPO agrees. According to the Macmillan Dictionary, a timeline means 1) "a plan of when something should happen or how much time something should take" and 2) "a line showing particular dates over a period of time, for example dates of historical events." While Rebel's submission may not have been everything DHEC intended, Rebel's response meets the minimal requirements of a timeline.

Therefore, the CPO finds Rebel's bid responsive to specification 3.7.

4. Allegation that Rebel's bid was responsive to 4.6 of the IFB, which read "Provide a detailed line item budget and narrative for the project specifying all charges."

Section 4.6 of the IFB required bidders to "Provide a detailed line item budget and narrative for the project specifying all charges." (Ex. 1, p. 16) Ms. Robinson found Rebel non-responsive to Section 4.6 because "Rebel Distributors only provided prices on the bidding Schedule in section VIII but failed to provide a detailed line item budget and narrative as required." (Ex. 4)

Rebel's protest letter stated, "We did in fact provide a line item bid per item with descriptions of the products to be repackaged. A narrative was also included 'Unit price includes all costs of labor, packaging material and freight to and from final destination'. Rebel also argued that its line item budget followed the format on page 30 of the IFB entitled VIII. BIDDING SCHEDULE/PRICE-BUSINESS PROPOSAL.

On its bidding schedule, Rebel provided unit price bids for re-packaging/re-labeling all four pharmaceuticals covered by the IFB. Further, Rebel explained that "[u]nit price includes all costs of: labor, packaging materials and freight to & from final destination at: 8229 Parkland Rd. Columbia, SC 29223". (Ex. 2, unnumbered page) While Rebel provided information specifying all charges, it did not provide a line item budget. However, the CPO fails to understand DHEC's need for an additional line item budget for the conduct of the work. Such further budgetary information seems superfluous. In

Protest by American Sterilizer Co., Case No. 1983-2, the Panel stated that a bid which fails to include an essential requirement of the IFB should be rejected as non-responsive. However, the Panel found that where the requirement is not essential its omission merely amounts to a minor informality or irregularity which the State should either waive or permit to be cured. Id.

Like in American Sterilizer, the CPO finds that 4.6 was not an essential requirement. Therefore, Rebel's omission should be waived as a minor informality. Accordingly, the CPO finds that Rebel's bid was responsive to specification 4.6.

5. Allegation that Rebel's bid was responsive to 4.8 of the IFB, which read "Provide a detailed description of how they plan to accomplish the re-labeling including a description of the plastic sleeve and where the labels will be placed on the product."

Section 4.8. of the IFB required bidders to "Provide a detailed description of how they plan to accomplish the re-labeling including a description of the plastic sleeve and where the labels will be placed on the product" (Ex. 1, p. 16) Ms. Robinson determined Rebel non-responsive to 4.8 because "The offeror did not provide an adequate response to this requirement. Rebel did not provide a detailed description of the re-labeling process they would use on the product."

Rebel's bid stated,

> **Re-label & Re-package Process Description**
>
> Per solicitation sec. IV subsection 4.8, the Relenza will be sleeved using clear plastic shrink-wrap with the revised expiration date and FDA statement covering the existing expiration date. No additional wording on the box will be concealed.
>
> Per solicitation sec. IV subsection 4.8, the Tamiflu will be re-labeled using the revised date and FDA statement which will be applied directly to the box (EA) with the revised expiration date and FDA statement covering the existing expiration date. No additional wording on the box will be concealed. (Ex. 2, p. 5)

Rebel's protest letter argues, "Our proposal did indicate the process that would be used and where the labels would be placed on the product." After-the-fact DHEC argues that Rebel was non-responsive to 4.8 because Tamiflu, unlike Relenza, comes in bottles, not boxes, and Rebel referenced relabeling Tamiflu boxes. The CPO finds that Rebel addressed the relabeling of both vaccines, and the reference to a box appears to be a typographical error, which amounts to a minor informality.

Therefore, the CPO finds Rebel's bid responsive to specification 4.8.

DETERMINATION

As detailed above, the CPO agrees that Rebel's bid should have been found to be responsive. However, the CPO finds that Rebel failed to prove that Ms. Robinson's determination that Rebel was not responsible, based upon its registration not being current on the FDA's registration website, was "clearly erroneous, arbitrary, capricious, or contrary to law" according to Section 11-35-2410(A). Rebel also failed to prove DHEC's determination that Safecor was responsible was "clearly erroneous, arbitrary, capricious, or contrary to law." Therefore, the protest is denied.

Voight Shealy

R. Voight Shealy
Chief Procurement Officer
for Supplies and Services

April 11, 2011
Columbia, S.C.

STATEMENT OF RIGHT TO FURTHER ADMINISTRATIVE REVIEW

Protest Appeal Notice (Revised October 2010)

The South Carolina Procurement Code, in Section 11-35-4210, subsection 6, states:

(6) Finality of Decision. A decision pursuant to subsection (4) is final and conclusive, unless fraudulent or unless a person adversely affected by the decision requests a further administrative review by the Procurement Review Panel pursuant to Section 11-35-4410(1) within ten days of posting of the decision in accordance with subsection (5). The request for review must be directed to the appropriate chief procurement officer, who shall forward the request to the panel or to the Procurement Review Panel, and must be in writing, setting forth the reasons for disagreement with the decision of the appropriate chief procurement officer. The person also may request a hearing before the Procurement Review Panel. The appropriate chief procurement officer and an affected governmental body shall have the opportunity to participate fully in a later review or appeal, administrative or judicial.

Copies of the Panel's decisions and other additional information regarding the protest process is available on the internet at the following web site: www.procurementlaw.sc.gov

FILE BY CLOSE OF BUSINESS: Appeals must be filed by 5:00 PM, the close of business. *Protest of Palmetto Unilect, LLC*, Case No. 2004-6 (dismissing as untimely an appeal emailed prior to 5:00 PM but not received until after 5:00 PM); *Appeal of Pee Dee Regional Transportation Services, et al.*, Case No. 2007-1 (dismissing as untimely an appeal faxed to the CPO at 6:59 PM).

FILING FEE: Pursuant to Proviso 83.1 of the 2010 General Appropriations Act, "[r]equests for administrative review before the South Carolina Procurement Review Panel shall be accompanied by a filing fee of two hundred and fifty dollars ($250.00), payable to the SC Procurement Review Panel. The panel is authorized to charge the party requesting an administrative review under the South Carolina Code Sections 11-35-4210(6), 11-35-4220(5), 11-35-4230(6) and/or 11-35-4410...Withdrawal of an appeal will result in the filing fee being forfeited to the panel. If a party desiring to file an appeal is unable to pay the filing fee because of hardship, the party shall submit a notarized affidavit to such effect. If after reviewing the affidavit the panel determines that such hardship exists, the filing fee shall be waived." 2010 S.C. Act No. 291, Part IB, § 83.1. PLEASE MAKE YOUR CHECK PAYABLE TO THE "SC PROCUREMENT REVIEW PANEL."

LEGAL REPRESENTATION: In order to prosecute an appeal before the Panel, a business must retain a lawyer. Failure to obtain counsel will result in dismissal of your appeal. *Protest of Lighting Services*, Case No. 2002-10 (Proc. Rev. Panel Nov. 6, 2002) and *Protest of The Kardon Corporation*, Case No. 2002-13 (Proc. Rev. Panel Jan. 31, 2003).

Shealy, Voight

From: Ari Greenwald [Ari@rebelrx.com]
Sent: Monday, March 07, 2011 2:05 AM
To: Shealy, Voight
Cc: WRIGHTSA@dhec.sc.gov; ROBINSMA@dhec.sc.gov
Subject: Rebel Distribtutors - PROTEST - Solicitation # 5400002478-Re-Bid

March 4, 2011

Solicitation # 540002478-Re-Bid

Mr. Voight Shealy

Chief Procurement Officer for Supplies and Services

South Carolina Budget and Control Board

Intent To Award Bid Protest

Mr. Shealy,

Pursuant to S. C. Code [Section 11-35-4210] [02-2A085-1], Rebel Distributors Corp. is submitting this letter in protest to the Bid Intent-to-Award on Solicitation # 540002478 - Re-Bid.

In response to our inquiry and questioning of the Intent to Award on Solicitation # 5400002478 - Re -Bid, we received a letter on march 2, 2011 from the Bureau of Business Management, Division of Procurement Services determining our Non-Responsiveness and Non-Responsibility to the above referenced solicitation and Intent to Award.

The following is our protest to the written response received.

We protest the following; Non-Responsible disqualification

Non Current FDA registration

"Under Paragraph 4.5 of the solicitation all offerors were required to provide evidence of

current FDA and South Carolina Board of Pharmacy Registrations."

We were deemed Non-Responsible; "The offeror's proposal contained only a 2006 FDA registration".

We protest the Non-Responsible disqualification for the following reasons;

A. Rebel indeed provided the only available hardcopy evidence; our registration from 2006.

"Under Paragraph 3.1, all bidders were required to have the registration status listed on the FDA website."

We were deemed Non-Responsible; "Rebel Distributor's 2009 registration was listed on the FDA's website as their most current registration as verified by the procurement officer prior to releasing the Intent to Award. Per 21 U.S.C. & 510 (b) (1) of the Federal Food, Drug, and Cosmetic Act and the implementation regulation, 21 CFR 207.21 (a), owners and operators must renew their registration information annually. Any potentially awarded contractor must be current with their FDA registration in order to be considered a responsible bidder and capable of providing the required services."

We protest the Non-Responsible disqualification for the following reasons;

A. Rebel was listed.

B. After contacting the FDA and multiple attempts to send in an update our registration was indeed updated.

C. The awardee was and still is not listed as current.

We are simply demonstrating with this information that relying on the website listing alone was not sufficient in determining whether a bid awardee has current registration status.

We protest the following; Non-Responsive disqualifications

Specifications:

1) 3.5 b. 1). Documentation must be provided that the products were maintained at a temperature control between 20-25°C (68-77°F) at all times. Rebel Distributor's did not address the requirement to provide documentation that the climate control was maintained at all times as the end of the term.

A. The language is referencing a past tense and instruction for once the product and shipment is complete. The language is not requesting any specific documentation.

4.7 Describe how they will provide documentation that the products were maintained at a temperature control between 20-25°C (68-77°F) at all times including during transit.

"Rebel did not provide an adequate description of their process for maintaining the temperature control at all times including during transit."

Our proposal stated;

Temperature Control and Documentation Description

Per solicitation sec. IV subsection 4.7, our facility monitors and maintains Temp/Humidity monitors throughout our production and warehousing facilities. Records are maintained for a minimum of three years. In transit temperature controls will feature temperature excursion alerts and temperature control. Documentation is maintained in the shipping manifest.

B. We protest this disqualification because the language in sec. IV subsection 4.7 specifically states "Describe how they will provide documentation that the products were maintained at a temperature control"; this item did not specifically ask for a description of our temperature control SOP or details on our temperature control panels or equipment.

2) 3.7 Provide a proposed timeline for the completion of this project

"Rebel Distributors did not respond adequately to this requirement; the offeror only acknowledged the start and completion dates as listed below."

Our proposal stated;

Start Date: Start date to begin within 30 days of solicitation award

Completion date: Re-label/ Repackage to be completed by June 1, 2011 or sooner.

C. We provided an adequate proposed timeline.

Webster's dictionary defines a timeline as: A time frame during which something is scheduled to happen

3) 4.6. Provide a detailed line item budget and narrative for the project specifying all charges

'Rebel Distributors only provided prices on the bidding Schedule in section VIII but failed to provide a detailed line item budget and narrative as required."

D. We did in fact provide a line item bid per item with descriptions of the products to be repackaged. A narrative was also included "Unit price includes all costs of labor, packaging material and freight to and from final destination"

4) 4.8. Provide a detailed description of how they plan to accomplish the relabeling including a description of the plastic sleeve and where the labels will be placed on the product.

" The offeror did not provide an adequate response to this requirement. Rebel did not provide a detailed description of the relabeling process they would use on the product."

Our proposal stated;

Re-label & Re-package Process Description

Per solicitation sec. IV subsection 4.8, the Relenza will be sleeved using clear plastic shrink-wrap with the revised expiration date and FDA statement covering the existing expiration date. No additional wording on the box will be concealed.

Per solicitation sec. IV subsection 4.8, the Tamiflu will be re-labeled using the revised date and FDA statement which will be applied directly to the box (EA) with the revised expiration date and FDA statement covering the existing expiration date. No additional wording on the box will be concealed.

E. Our proposal did indicate the process that would be used and where the labels would be placed on the product.

Rebel Distributors contends that it complied with all the requirements to be awarded this solicitation and is aggrieved that it did not receive the Intent to Award.

Ahron Greenwald

EVP / COO

Rebel Distributors Corp.

805-214-0900